03-SAR-065

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Terrance G. Alexander, Director

February 6, 2003

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Minh Thomas
Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Road, E-79
Atlanta, GA 30333

Dear Ms. Thomas:

The University of Michigan appreciates the opportunity to comment on, and offers our support for the February 3 comments from AAU/ACE/COGR and the January 21 comments from HHMI, on the matter of the Interim Final Rule on Possession, Use, and Transfer of Select Agents and Toxins, 67 FR 76886. We were able to review and comment on the documents and we feel they accurately reflect the needs, concerns, and unified recommendations of the academic institutions the new regulations will affect. We hope you will give weight to our institutional support and will give the joint recommendations due consideration toward improvements in the regulatory criteria and processes.

As the Responsible Officials for our registered facility over the past 6 years, we have been on the front line of institutional preparedness to deal with the biosecurity oversight responsibilities and regulatory burden of these hazardous materials. In that regard, we have found the CDC to be extraordinarily good at listening to feedback and suggestions for improvements to the regulatory criteria and practices. Of late, however, the CDC has been under enormous pressures to perform in ways they were not originally designed to accommodate.

We were disappointed to see that the Interim Final Rule summarily rolls back many of the exemptions previously identified by the CDC/LR-SAT for vaccine-related materials that have no valid reason for being defined as select agents. For instance B. anthracis Sterne strain has been a safe and effective vaccine organism for decades, and an extremely useful tool for research studies into the activation mechanisms and biochemical pathways of this important pathogen. CDC is now forced to rescind and reconsider exemptions they had already spent several years debating and developing. Their determinations had been posted out to the research community and they made sense to those who were affected. We feel it is unwise to negate this good work and compel a reissuance of previous determinations, especially with the short time that has been allowed for this process under the new regulatory deadlines. We recommend this be corrected and the vaccine-strain determinations remain as previously stated by the CDC.

Sincerely,

Michael G. Hanna
Manager - Biological & Laboratory Safety

Terrance G. Alexander
Director